

Announced Care Inspection Report 9 January 2019



Therapie Optilase

Type of service: Independent Hospital (IH) - Refractive Laser Eye Surgery, Cosmetic Laser and Private Doctor Service

Address: Unit 0, Erneside Shopping Centre, Enniskillen, BT74 6JQ

Tel No: 08000 121565

Inspector: Stephen O'Connor

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

Therapie Optilase is an independent hospital providing a laser hair removal service. There are no overnight beds provided in this establishment. Ms Gemma Knightly, registered manager, confirmed that refractive laser eye surgery and the private doctor services related to laser eye surgery are no longer provided in this establishment. The laser equipment used during refractive laser eye surgery has been removed from the establishment.

Therapie Optilase provides a range of cosmetic/aesthetic treatments. This inspection focused solely on the treatment that falls within regulated activity and the categories of care for which the establishment is registered.

Ms Knightly confirmed that the equipment in place at the time of the previous inspection has been decommissioned and two new lasers have been purchased.

Laser equipment

Manufacturer: Cynosure
 Model: Elite+
 Serial Number: ELM+1947
 Laser Class: 4

Manufacturer: Cynosure
 Model: Elite+
 Serial Number: ELM+1977
 Laser Class: 4

Laser protection advisor (LPA):

Mr Alex Zarneth

Laser protection supervisor (LPS):

Ms Gemma Knightly

Medical support services:

Dr Tapan Patel

Authorised operators:

Ms Gemma Knightly, Ms Catriona Curry, Ms Clare Monaghan, Ms Richella Timoney, Ms Sara Kavourmas

Types of treatment provided:

Hair removal

3.0 Service details

Organisation/Registered Provider: Therapie Optilase (Enniskillen) Ltd	Registered Manager: Ms Gemma Knightly
Responsible Individual: Mr Phillip McGlade	
Person in charge at the time of inspection: Ms Gemma Knightly	Date manager registered: 17 November 2016
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PD Private Doctor	

4.0 Inspection summary

An announced inspection took place on 9 January 2019 from 09:50 to 13:20.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland)

2011, The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: patient safety in respect of staff training and development; safeguarding; infection prevention and control; laser safety arrangements; the management of medical emergencies; and the environment. Other examples included: the management of the patients' care pathway; communication; records management and engagement to enhance the patients' experience.

Two areas for improvement against the regulations and three against the standards have been made. The areas for improvement against the regulations relate to the responsible individual or their nominated representative unannounced quality monitoring visits and to submit a variation to registration application to remove the private doctor (PD) category of care. One area for improvement against the standards made during the previous inspection in relation to installing wall mounted disposable hand towel dispensers has not been met and is stated of the second time. Two further areas for improvement against the standards made are in relation to consulting with the appointed laser protection advisor to ensure the local rules include details of total blocking shields and to submit the insurance certificate in respect of employers and public liability.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	2	3

Details of the Quality Improvement Plan (QIP) were discussed with Ms Gemma Knightly, registered manger, as part of the inspection process. The timescales for completion commence from the date of inspection.

Enforcement action did not result from the findings of this inspection.

4.2 Action/enforcement taken following the most recent care inspection dated 14 March 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 14 March 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the establishment was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- the returned QIP from the previous care inspection

Questionnaires were provided to patients prior to the inspection by the establishment on behalf of RQIA. Returned completed patient questionnaires were analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire prior to the inspection. Returned completed staff questionnaires were analysed prior to and following the inspection.

A poster informing patients that an inspection was being conducted was displayed.

During the inspection the inspector met with Ms Gemma Knightly, registered manager and authorised operator and another authorised operator. A tour of the premises was also undertaken.

A sample of records were examined during the inspection in relation to the following areas:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- care pathway
- communication
- management and governance arrangements
- practising privileges
- maintenance arrangements

Areas for improvement identified at the last care inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to Ms Knightly, registered manager at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 14 March 2018

The most recent inspection of the establishment was an announced care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 14 March 2018

Areas for improvement from the last care inspection		
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		Validation of compliance
Area for improvement 1 Ref: Standard 20 Stated: First time	The registered person shall ensure that a wall mounted disposable paper towel dispenser is installed adjacent to the wash hand basin in the laser room.	Not met
	Action taken as confirmed during the inspection: It was observed that disposable hand towels were in baskets beside the wash hand basin in the laser rooms. This area for improvement has not been met and is stated for the second time.	
Area for improvement 2 Ref: Standard 48.10 Stated: First time	The registered person shall ensure that client records are accurately completed on each occasion that laser treatment is provided to the client.	Met
	Action taken as confirmed during the inspection: Review of four randomly selected treatment records evidenced that they were fully completed. All treatments recorded in these records were recorded in the laser register.	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

As stated previously it was confirmed that refractive laser eye surgery is no longer provided in the establishment. The only laser service provided relates to a laser hair removal service.

Discussion with Ms Knightly, confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients.

Ms Knightly confirmed that laser treatments are carried out by authorised operators. A register of authorised operators for the laser equipment is maintained and kept up to date.

Discussion with Ms Knightly and review of documentation evidenced that two new authorised operators have been recruited since the previous inspection. Review of documentation evidenced that the newly recruited authorised operators had completed an induction programme.

A review of training records evidenced that all authorised operators had up to date training in core of knowledge, safe use and application of the equipment in use, basic life support, infection prevention and control, safeguarding adults and fire safety.

Ms Knightly confirmed that all staff are authorised operators and should support staff be recruited in the future, they would receive laser safety awareness training.

Recruitment and selection

As discussed, two authorised operators have been recruited since the previous inspection. Review of records in respect of the newly recruited authorised operators evidenced that all records as outlined in regulation 19 (2) schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 had been sought and retained

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Safeguarding

It was confirmed that laser treatments are not provided to persons under the age of 18 years.

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was confirmed that the safeguarding lead has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

Laser safety

A laser safety file is in place which contains all of the relevant information in relation to laser equipment.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires during November 2019.

It was noted that the medical treatment protocols on file were produced by a named registered nurse. This is not in keeping with standard 48.3 of the Minimum Care Standards for

Independent Healthcare Establishments (July 2014) which states that laser procedures should only be carried out by authorised operators in accordance with medical treatment protocols produced by a named medical practitioner. This was brought to the attention of Ms Knightly. Prior to the conclusion of the inspection medical treatment protocols produced by Dr Tapan Patel, valid between July 2017 and July 2019 were sourced. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

Up to date local rules are in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the premises during December 2018 and no recommendations were made.

Ms Knightly as the laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator, who is suitably skilled to fulfil the role, to deputise for the LPS in their absence. Discussion with Ms Knightly confirmed that systems are in place to ensure other authorised operators are aware of who the LPS is on duty.

The treatment rooms in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The doors to the treatment rooms are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The lasers are operated using a key. Arrangements are in place for the safe custody of the laser keys when not in use. Protective eyewear is available for the client and operator as outlined in the local rules. It was noted that total blocking shields were available in the establishment; however, these are not referenced in the local rules. An area for improvement against the standards has been made in this regard.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has a laser register which is completed every time the equipment is operated and includes:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure
- any accident or adverse incident

It was confirmed that as both laser machines are new they are covered under the manufacturer's warranty and that arrangements are in place with the supplier to service the machines when due. The installation commissioning reports dated 15 November 2018 were reviewed during the inspection.

Management of medical emergencies

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency.

The policy for the management of medical emergencies reflected best practice guidance.

Infection prevention and control (IPC) and decontamination procedures

The laser treatment rooms were clean and clutter free. Completed cleaning schedules were in place including a monthly deep cleaning log. Discussion with staff evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As stated, disposable hand towels were stored in baskets beside hand wash basins. An area for improvement against the standards made during the previous care inspection in this regard has not been met and is stated for a second time.

As discussed previously, authorised operators have up to date training in IPC.

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits have been carried out including:

- environmental
- hand hygiene

The compliance rate was noted to be high and an action plan was in place for areas of non-compliance.

There were a range of IPC policies and procedures in place.

Environment

The premises were maintained to a good standard of maintenance and décor. Arrangements are in place for maintaining the environment.

A carbon dioxide (CO₂) fire extinguisher was available which has been serviced within the last year.

Staff demonstrated that they were aware of the action to take in the event of a fire.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff recruitment, induction, appraisal, laser safety, risk management and the environment.

Areas for improvement

The local rules should be reviewed to ensure they include the details of the appropriate total blocking shields to be provided.

Install wall mounted disposable paper towel dispensers adjacent to the wash hand basins in the laser treatment rooms.

	Regulations	Standards
Areas for improvement	0	2

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment has a list of fees available for each laser procedure.

Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner, with their consent, for further information if necessary.

Four client care records were reviewed. There is an accurate and up to date treatment record for every client which includes:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

Observations made evidenced that client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Discussion with Ms Knightly and staff and a review of the management of records policy confirmed that clients have the right to apply for access to their clinical records in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate Information Commissioners Office (ICO) regulations and Freedom of Information legislation.

The establishment is registered with the ICO.

Communication

As discussed, there is written information for clients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

Staff confirmed that management is approachable and their views and opinions are listened to. Ms Knightly confirmed that staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained. Ms Knightly confirmed that complaints or incidents would be reviewed and that any learning would be disseminated to staff.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records and ensuring effective communication between clients and the authorised operator.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Ms Knightly and staff confirmed that during the consultation and treatment process, clients are treated with dignity and respect. The consultation and treatment is provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely.

Client satisfaction surveys are carried out by the establishment routinely. The results of these are collated to provide a summary report which is made available to clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that clients were highly satisfied with the quality of treatment, information and care received.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining client confidentiality ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Arrangements were in place to facilitate annual staff appraisal. There was a nominated individual with overall responsibility for the day to day management of the service.

There was no evidence of the six monthly unannounced visits by the responsible individual or their nominated representative, as outlined in Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended. An area for improvement against the regulations has been made in this regard.

As discussed in section 2.0 of this report Ms knightly confirmed that refractive laser eye surgery and the private doctor services related to laser eye surgery are no longer provided in this establishment. A variation to registration application should be submitted to RQIA to remove the private doctor (PD) category of care to ensure that the categories of care registered reflect the services being provided in the establishment. An area for improvement against the regulations has been made in this regard.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on an annual basis. Staff spoken with were aware of the policies and how to access them.

Ms Knightly confirmed that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Ms Knightly demonstrated good awareness of complaints management.

Discussion with Ms Knightly confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

Discussion with Ms Knightly confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. Ms Knightly confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

Ms Knightly, registered manager demonstrated a clear understanding of her role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. Ms Knightly confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

Observation of insurance documentation confirmed that current insurance policies were in place in relation to professional indemnity. Documentation was available in relation to employers and public liability, however, the date the policy expires could not be identified. An area for improvement against the standards has been made in this regard.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

Six monthly unannounced visits by the responsible individual or their nominated representative, as outlined in Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended should be carried out. Written reports of the unannounced visits should be available for inspection.

A variation to registration application to remove the private doctor (PD) category of care should be submitted to RQIA.

The insurance certificate relating to employers and public liability should be submitted to RQIA.

	Regulations	Standards
Areas for improvement	2	1

6.8 Equality data

Equality data

The arrangements in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients was discussed with Ms Knightly.

6.9 Patient and staff views

Twenty clients submitted questionnaire responses to RQIA. All 20 clients indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All 20 clients indicated that they were very satisfied with each of these areas of their care. No comments were included in submitted questionnaire responses.

Four staff submitted questionnaire responses to RQIA. All four staff members indicated that they felt client care was safe, effective, that clients were treated with compassion and that the service was well led. All staff indicated that they were very satisfied with each of these areas of client care. Comments included in submitted questionnaire responses are as follows:

- “I love working for Therapie great company always looked after very well.”
- “I feel Therapie is very good company to work for and make sure everything is done correctly.”
- “Training is very good from Therapie and client care is excellent.”

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Gemma Knightly, registered manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of a refractive laser eye surgery service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 Ref: Regulation 26 Stated: First time To be completed by: 06 March 2019	<p>The registered person shall ensure that six monthly unannounced visits by the responsible individual or their nominated representative, as outlined in Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended, are carried out.</p> <p>Written reports of the unannounced visits should be available for inspection.</p> <p>Ref: 6.7</p>
Response by registered person detailing the actions taken: These have already been started and will be carried out twice a year	
The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005	
Area for improvement 2 Ref: Regulation 12 Stated: First time To be completed by: 06 March 2019	<p>The registered person shall submit a variation to registration application to remove the private doctor (PD) category of care to ensure that the categories of care registered with RQIA reflect the services being provided in the establishment.</p> <p>Ref: 6.7</p>
Response by registered person detailing the actions taken: This has already been submitted to the registration team.	
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (2014)	
Area for improvement 1 Ref: Standard 20 Stated: Second time To be completed by: 06 March 2019	<p>The registered person shall ensure that a wall mounted disposable paper towel dispenser is installed adjacent to the wash hand basin in the laser room.</p> <p>Ref: 6.2 and 6.4</p>
Response by registered person detailing the actions taken: Has been actioned and up on the walls at sinks	
Area for improvement 2 Ref: Standard 48.4 Stated: First time	<p>The registered person shall consult with the appointed laser protection advisor (LPA) to ensure that the details of the total blocking shields provided are included in the local rules.</p> <p>Ref: 6.4</p>
Response by registered person detailing the actions taken:	

To be completed by: 06 February 2019	This has been actioned by Dr Alex Zarneh
Area for improvement 3 Ref: Standard 6.7 Stated: First time	The registered person shall submit the insurance certificate relating to employers and public liability upon return of this quality improvement plan (QIP). Ref: 6.7
To be completed by: 06 March 2019	Response by registered person detailing the actions taken: This has been sent on to the inspector Stephen O Connor

Please ensure this document is completed in full and returned via Web Portal



The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
Twitter @RQIANews